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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,571	06/09/2000	BERNARD CALAS	19904-009	2070

7590 09/16/2004

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/485,571	CALAS ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *18-25,29,30 and 32-36*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See attached Interview Summary*

Continuation of 2. NOTE: The amendment to the claims does not resolve the current issues under 35 USC 112, first and second paragraphs. It also raise new issues regarding the fragment of SEQ ID NO:23 (at least 5 successive amino acids), which require further consideration and search. In the amendment of August 27, 2004, claims 18, 20, 24, 29, 30 and 32-34 have been amended, claims 21-23, 25, 35 and 36 have been cancelled, and new claims 37 and 38 have been added. Applicants' response has been fully considered, however, claims 18-20, 24, 29, 30, 32-34, 37 and 38 are rejected under 35 USC 112, first and second paragraphs.

If applicants' amendment were entered, it would have the following response:

1. Claims 18-20, 24, 29, 30, 32-34, 37 and 38 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for a linear peptide of SEQ ID NO:23 obtained from an antibiotic peptide; a specific compound of formula (IV), wherein A is the peptide sequence of SEQ ID NO:23, Z is biotin or doxorubicin, m=1 and n=0; or a method of vectoring a specific active substance such as biotin or doxorubicin to a target cell using the conjugate of biotin-peptide or doxorubicin-peptide, wherein the peptide is SEQ ID NO:23, does not reasonably provide enablement for a moiety of the linear peptide to vectorize active sustances, wherein the moiety of the linear peptide is a fragment of SEQ ID NO:23 having at least 5 successive amino acids; a compound of formula (IV), wherein A is SEQ ID NO:23 or a fragment of SEQ ID NO:23 having at least 5 successive amino acids; a pharmaceutical composition comprising the compound of formula (IV); a diagnostic agent comprising the compound of formula (IV); or a method of vectoring an active substance to a target cell, cell compartment, or organ using a conjugate of active substance and a linear peptide of SEQ ID NO:23 or a fragment of SEQ ID NO:23 having at least 5 successive amino acids, wherein the active substance, the signal agent and the target cell, cell compartment, or organ are not specifically defined. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification only indicates certain peptides of protegrin and tachyplesin (Tables I and II, e.g., SEQ ID NO:23), the conjugates of the peptide with doxorubicin or biotin, and the internalization abilities of these peptides in different cell lines, which was the basis for vectoring an active substance in an organism (Examples 1-4). However, the specification fails to identify and describe a compound of formula (IV) containing various active substances and various signal agents, and to demonstrate the fragments of SEQ ID NO:23 have the activity of vectoring active substance to specific cell compartments, cells or organs. Please see paragraph 6 of the previous Office Action dated March 3, 2004 for details.

In response, applicants indicate the term "an analog" for the analogs of SEQ ID NO:23 has been deleted, the added "the moiety of said linear peptide" is supported by the specification (page 9, lines 28), and formula (IV) has been consistent with the specification; and the claims have been amended to correct the issue of new matter (pages 7-8 of the repsone). The repsonse has been considered, however, the argument is not fully persuasive because the specification has not demonstrated the moiety of linear peptide having at least 5 successive amino acids exhibits the activity of vectoring an active substance, nor has identifed and described various compounds of formula (IV) containing numerous active substances and signal agents. Therefore, the full scope of the claims are not enabled. Regarding the new matter, formula (IV) has been corrected in the claim, thus, the rejection is withdarwn.

2. Claim 20 is rejected under 35 USC 112, second paragraph. Claim 20 is indefinite because of the use of the term "target", it is not clear what the target is.

3. Claims 24, 29, 30, 32-34, 37 and 38 are indefinite because of the use of the term "a particular cell compartment, a particular cell type or a particular organ" or "said signal agent having an affinity towards a particular cell type, cell compartment or a specific tissue or organ, or the ability to recognize a specific determinant present on a particular cell type, cell compartment or a specific tissue or organ". The term cited above renders the claim indefinite, it is not clear which cell compartment, cell type, tissue or organ is as to "a particular cell compartment, a particular cell type or a particular organ" or "a particular cell type, cell compartment or a specific tissue or organ"; what the determinant is; and how the active substance coupled with the peptide can target at a particular cell compartment, a particular cell type or a specific tissue or organ without identifying the cell compartment, cell type, tissue or organ. Claims 30, 32-34 and 38 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

In response, applicants indicatethe the pending claims are read in light of the specification, thus they are definite (page 8 of the response). The repsonse has been considered, however, the argument is not fully persuasive because neither the specification nor the claim has defined the term.

4. Claim 30 recites the limitation "lysine" in line 5. There is insufficient antecedent basis for this limitation in the claim because the linear peptide (SEQ ID NO:23) does not have lysine in the sequence.

5 Claim 38 is indefinite because of the use of the term "and/or". The term "and/or" renders the claim indefinite, it is unclear whether the limitation after "and/or" is included or not, and if included is to be read as an alternative "or" or the conjunctive "and".

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, the rejection of claims 18 and 19 under 35 USC 112, second paragraph. .

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issue under 35 USC 112, first and second paragraphs .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CMK
September 10, 2004

JON WEBER
SUPERVISORY PATENT EXAMINER